

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

(Use as many sheets as necessary)

Sheet	1	of	2
-------	---	----	---

Complete if Known

Application Number	Based on PCT/JP2004/014475
Filing Date	Intl. Filing 01-OCT-2004
First Named Inventor	T. Asakawa
Art Unit	tba
Examiner Name	tba
Attorney Docket Number	3197US0P

U. S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

[illegible]

**Examiner
Signature**

Darryl C. Sutton

Digitally signed by Darryl C. Sutton
DN: cn=Darryl C. Sutton, c=US, o=USPTO, email=darryl.sutton@uspto.gov
Date: 2007.10.25 18:00:45 -04'00'

Date Considered

10/25/2007

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

10/25/2007 10:00:00 AM

PTO/SB/088 (08-03)

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Application Number	Based on PCT/JP2004/014475
		Filing Date	Intl. Filing 01 OCT 2004
		First Named Inventor	T. Asakawa
		Art Unit	tba
		Examiner Name	tba
Sheet 2 of 2	Attorney Docket Number	3197US0P	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
/D.S./	A2	J. LARSEN, MD., et al., "Glucagon-Like Peptide-1 Infusion Must be Maintained for 24 h/day to Obtain Acceptable Glycemia in type 2 Diabetic Patients Who are Poorly Controlled on Sulphonylurea Treatment", Diabetes Care, (August 2001), 24(8): 1416-1421	
	A3	M.A. NAUCK, MD., et al., "Influence of Glucagon-Like Peptide 1 on Fasting Glycemia in Type 2 Diabetic Patients Treated with Insulin After Sulphonylurea Secondary Failure", Diabetes Care, (November 1998), 21(11): 1925-1931	
	A4	V. TRISCHITTA, et al., "Comparison of Combined Therapies in Treatment of Secondary Failure to Glyburide", Diabetes Care, (April 1992), 15(4): 539-542	
	A5	G. FANGHANEL, MD., et al., "Metformin's Effects on Glucose and Lipid Metabolism in Patients with Secondary Failure to Sulphonylureas", Diabetes Care, (November 1996), 19(11): 1185-1189	
	A6	H. KIYONO, et al., "Analysis of Functional Relation of Pancreatic Beta-Cell ATP-Sensitive K ⁺ Channels and Sulphonylurea Receptor, and Development of Oral Antidiabetic Drug Based on New Action Mechanism", Suzuken Memorial Foundation, (2001), pages 147-149, English Translation attached.	✓
	A7	K. YAMADA, "Appropriate Use and Combined Use of Oral Hypoglycemic Agents, (2002), Vol. 36, pp. 292-296, English Translation of Tonyobyogaku no Shinpo attached.	✓
	A8	J. KAN, et al., "The Effect of Ultra-Rapid-Acting Insulin Secretagogue, Nateglinide (Na), in Patients with Type 2 Diabetes That Seems to Be Secondary Ineffectiveness of SU Drugs", The Journal of the Japan Diabetic Society, (2000), 43 (Supple. 1), p. S-120, English Translation attached.	✓
	A9	K. MIMURA, et al., "Experience of Use of Rapid-Acting Postprandial Hypoglycemic Drug (Nateglinide) in Type 2 Diabetic Patients Who Showed Secondary Effectiveness of Sulphonylurea Drugs", Nippon Taishitsugaku Zasshi, (2001), 63(1-2): 52; English Translation attached.	✓
/D.S./	A10	Y. KITAHARA, et al., "A Rapid-Onset/Short-Duration Insulin Secretagogue as a Physiologic Postprandial Blood Glucose Regulator", Saibo (Cells), 2000, 32(12): 480-483; English Translation Attached	✓

Examiner Signature	Darryl C. Sutton	Digitally signed by Darryl C. Sutton DN: cn=Darryl C. Sutton, c=US, o=USPTO, email=darryl.sutton@uspto.gov Date: 2007.10.25 18:02:18 -04'00'	Date Considered	10/25/2007
--------------------	------------------	---	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
Date Submitted: **NOV 20 2006**

(use as many sheets as necessary)

1 of 1

Complete if Known

Application Number	10/573,868
Filing Date	10/1/2004
First Named Inventor	Tomoko Asakawa
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	074129-0541

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/D.S./	B1	7,034,039	B2	Oi et al.	

UNPUBLISHED U.S. PATENT APPLICATION DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Application Document Serial Number-Kind Code ² (if known)	Filing Date of Cited Document MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ Number ⁴ Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶

Examiner
Signature**Darryl C. Sutton**

Digitally signed by Darryl C. Sutton
DN: cn=Darryl C. Sutton, c=US, o=USPTO, email=darryl.sutton@uspto.gov
Date: 2007.10.25 18:03:58 -04'00'

Date
Considered**10/25/2007**

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: April 30, 2007 (Use as many sheets as necessary)		Complete if Known	
Application Number		10/573,868	
Filing Date		10/1/2004	
First Named Inventor		Tomoko Asakawa	
Art Unit		1614	
Examiner Name		Ardin H. Marschel	
Attorney Docket Number		074129-0541	

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
/D.S./	C1	2003-073728 A1	04/17/2003	VAN POELJE et al.	
/D.S./	C2	2006-039974 A1	02/23/2006	AKIYAMA et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
/D.S./	C3	EP 1 422 293 A	05/26/2004	Hoffmann La Roche		
/D.S./	C4	WO 2004/024184 A	03/25/2004	Takeda Chemical Ind. Ltd.		A

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶

Examiner Signature	Darryl C. Sutton	Digitally signed by Darryl C. Sutton DN: cn=Darryl C. Sutton, c=US, o=USPTO, email=darryl.sutton@uspto.gov Date: 2007.10.25 18:05:16 -04'00'	Date Considered	10/25/2007
--------------------	------------------	--	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.